Mesure Technology Co., Ltd.

510(K) SUMMARY

OCT - 4 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, and the relevant 510(k) submission guidance on September 30, 2011.

The assigned 510(k) number is: K112703 .

Submitter's Identifications:
Company: Mesure Technology Co., Ltd.
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Contact person: Rack Yu.
Telephone Number : +886-2-8512-2747

1. Name of the Device:
   Trade Name : Shaker Digital Thermometer, model ST8S Series
   Common Name : Shaker Digital Thermometer, model ST8S Series.
   Classification Name : Clinical Electronic Thermometer

2. Information of the 510(k) Cleared Device (Predicate Device):
   Digital Clinical Thermometer, model ST-833A, and ST-834A (K981337)

3. Device Description:
   The shaker digital thermometer, model ST8S Series, are the electronic thermometers by using a thermistor as the temperature sensor. The signal of sensor is calculated and displayed by an ASIC (Application Specific IC) – controlled circuit, which is considered the hard-wire control instead of programmable control.

   From the construction point of view, the digital thermometer comprises of a thermistor for measuring sensor, a reference resistor for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

   ST8S uses a hand shaking power generation mechanism to generate the electrical power required for short time temperature measurement operation. Whenever the generated power is low, the device as well as LCD display are switched off automatically. Regarding the performance of ST8S Series, it was designed and verified according to the US standard ASTM E 1112-00.

4. Intended Use:
   The device measures the body temperature of a patient by means of a sensor (transducer) coupled with electronic signal amplification, conditioning and digital LCD (display) unit. The device is reusable and intended for oral, axillary or rectal temperature measurements.

5. Contraindication:
   For oral and rectal temperature measurement, the FDA 510(K) cleared and listing disposable probe cover shall be used for each measurement to prevent the risk of cross-infection

6. Compatible Accessory :
   Yu Long Sheng Disposable Thermometer Sheath(Probe Cover); model YLS-01(K012508) ; This compatible accessory shall be used for the oral and rectal temperature measurement.

7. Comparison to the 510(k) Cleared Device (Predicate Device):
   Since the new models ST8S Series were developed from the cleared device ST-833A, and ST-834A through the design control procedures of Measure Technology Co., Ltd. with only the small change in power supply system and device housing, the new device is substantial equivalence to that of device being modified, ST-833A, and ST-834A.

8. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
   Compliance is ensure via the following voluntary standard testing reports:
   1> ASTM E1112-00 for device performance compliance tested by manufacturer
   2> EN/IEC 60601-1 for electrical safety compliance tested by accredited laboratory
   3> EN/IEC 60601-1-2 for EMC compliance tested by accredited laboratory.

9. Conclusions

   The Mesure shaker digital thermometer, models ST8S Series have the same intended use and technological characteristics as the cleared device of Measure's model ST-833A, and ST-834A. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device. Therefore; we concluded that the Mesure shaker digital thermometer, models ST8S Series of model is substantial equivalent to the Measure's model ST-833A, and ST-834A(K981337)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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OCT - 4 2011

Re: K112703
Trade/Device Name: Shaker Digital Thermometer, Models ST8S Series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 14, 2011
Received: September 16, 2011

Dear Mr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K112703

Device Name: Shaker Digital Thermometer, Models ST8S Series

Indications For Use:

The device measures the body temperature of a patient by means of a sensor (transducer) coupled with electronic signal amplification, conditioning and digital LCD (display) unit. The device is reusable and intended for oral, axillary or rectal temperature measurements.

Contraindication:

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Prescription Use ____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/3/11
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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